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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,754

05/19/2006

Joel Slade

4-33247A

1611

1095

7590

03/03/2008

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

HAVLIN, ROBERT H

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

03/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,754	Applicant(s) SLADE ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims: Claims 1-17 are currently pending. Claims 1 and 9 were amended; claims 15-17 were newly presented.

Priority: This application is a 371 of PCT/EP04/06915 (06/25/2004) which claims benefit of US 60/482,686 (06/26/2003).

IDS: No IDS was filed with this application.

CLAIM REJECTIONS

Double Patenting

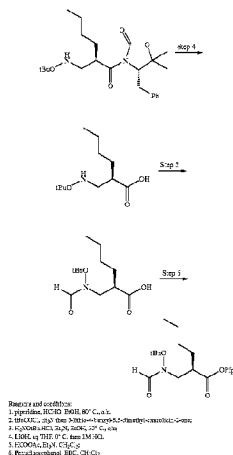
Claims 1-14 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 and 26-29 of copending Application No. 10/527628 and claims 6-11 and 20-35 of copending application 10/544919. Applicant indicates they will file a terminal disclaimer upon allowance of the pending claims. This rejection is maintained and expanded to include the newly presented dependent claims 15-17.

Claim Rejections - 35 USC § 103

Claims 1-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (WO 02/102790) in view of Beckett et al. (US 6,503,897), Jacobs et al. (US 7,148,242), Fuhrer et al. (US 4,613,676), Shiraishi et al. (US 5,891,895), Goodman et al. (Biopolymers - Peptide Science, 2001, Vol. 60, p. 229-245), and Digenis et al. (J. Med. Chem. 1986, 29, 1468-1476). This rejection is maintained and expanded to include the newly presented dependent claims 15-17.

1. Applicant argues that the secondary references fail to teach the limitations of:
amide hydrolysis prior to formylation; formation of a free base from a salt; or formation
of a carboxylic acid salt prior to coupling.

a. Beckett teaches amide hydrolysis prior to formylation as recited in the

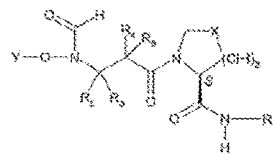


prior office action:

b. Patel teaches on page 16 the formation of a free base from a salt.

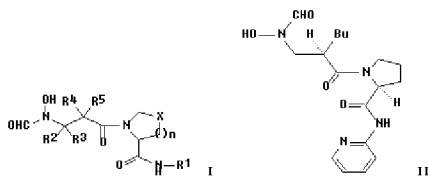
c. Fuhrer teaches on cols 30-32 the formation of a carboxylic acid salt prior to the formation of an amide bond.

2. Applicant also argues that because the compounds of the references are structurally dissimilar to the compounds of the present application, one of skill in the art would not be motivated to apply the procedures of these references. The instant claims

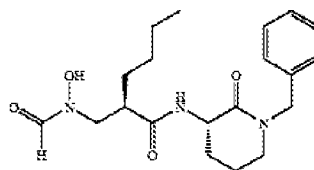


are drawn to methods of making compounds of the formula:

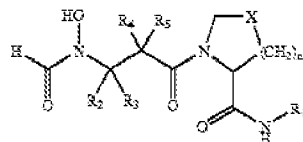
- a. Patel teaches the compounds:



- b. Beckett teaches compounds:



- c. Jacobs:

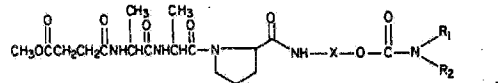


- d. Fuhrer:  ,  , etc.

- e. Shiraishi teaches the hydroxypyridine modification.

- f. Goodman teaches peptidomimetics similar to the instant claims.

- g. Deginis teaches compounds such as



Therefore, all of the compounds share substantially chemical similarity such that one of ordinary skill in the art would be motivated to look to the references.

4. Applicant also asserts that the examiner has used hindsight reconstruction in the determination of obviousness. The examiner counters that the level of ordinary skill in the synthetic chemical arts is very high and particularly in the area of peptide formation

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and related transformations the level of ordinary skill is even higher. Thus, one of ordinary skill has an intimate familiarity with reactions such as those argued as being distinguishing from the prior art. Amide hydrolysis prior to formylation; formation of a free base from a salt; and formation of a carboxylic acid salt prior to coupling are all well within the technical grasp of one of ordinary skill in the art and there is a reasonable expectation that one of ordinary skill in the art would draw on this knowledge and arrive at the claimed invention. Therefore, the determination of obviousness properly incorporated the level of skill in the art along with the exemplary teachings of the prior art to arrive at the claimed invention without hindsight reconstruction.

Conclusion

All claims are rejected. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Cecilia Tsang can be reached at (571)-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626